UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, *et al.* *ex rel*. SAPF, LLC and BRIAN BROUSSEAU Plaintiffs, v. AMGEN LLC, ASHFIELD HEALTHCARE LLC, UDG HEALTHCARE, ACCREDO SPECIALTY PHARMACY, EXPRESS SCRIPTS HOLDING COMPANY, UNITEDBIOSOURCE CORPORATION, MCKESSON CORPORATION, INVENTIV HEALTH INC., AND THE LASH GROUP, Defendants.	Civil Action No. 16-5203

MEMORANDUM OF LAW IN SUPPORT OF THE UNITED STATES' MOTION TO DISMISS

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The United States of America ("United States" or "Government") submits this memorandum of law in support of its Motion to Dismiss all claims brought on behalf of the United States by SAPF, LLC and Brian Brousseau under the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"), pursuant to 31 U.S.C. § 3730(c)(2)(A).[1] As discussed more fully below, this action was spearheaded by a professional relator who has filed eleven *qui tam* actions throughout seven judicial districts, each raising substantially the same allegations under the FCA. Having completed its investigation, and finding the allegations to lack sufficient merit to justify the cost of investigation and prosecution and otherwise to be contrary to the public interest, the United States now seeks to dismiss relators' FCA claims.

I. BACKGROUND AND PROCEDURAL HISTORY

A. The NHCA Group *Qui Tam* Actions

This *qui tam* action was filed on September 30, 2016 by co-relators Brian Brousseau, a former Amgen employee, and SAPF, LLC, a limited liability company established for the sole purpose of serving as a named relator in this action. SAPF, LLC is a shell company established by Venari Partners, LLC, dba National Health Care Analysis Group ("NHCA Group"), a limited liability corporation that is itself comprised of member limited liability companies formed by investors and former Wall Street investment bankers. *See* accompanying Declaration of Brian J. McCabe ("McCabe Decl."), ¶¶ 2-3 and Exhibit A (email from attorney Marc Mukasey, counsel

[1] Relators have brought claims on behalf of certain Medicaid-participating states under their respective state false claim statutes. Undersigned counsel does not represent the named state plaintiffs; however, Kerry Muldowney Ascher, counsel for the state of Texas and representative of the National Association of Medicaid Fraud Control Units, has represented to the United States that all named state plaintiffs consent to the United States' motion to dismiss so long as it is without prejudice to the states, with the exception of New Jersey, which takes no position on the motion.

for NHCA Group, describing corporate structure of NCHA Group); and Exhibit B (visual aid depicting NHCA Group relators and corporate organization).

Acting through its numerous shell company relators, NHCA Group has filed eleven *qui tam* complaints against a total of thirty-eight different defendants for essentially the same alleged conduct. In addition to this action, the other complaints include:

- *U.S. ex rel. SMSF, LLC, et al. v. Biogen, Inc., et al.*, No. 1:16-cv-11379 (D. Mass.)
- *U.S. ex rel. SMSPF, LLC v. EMD Serono, Inc., et al.*, No. 16-cv-5594 (E.D. Pa.)
- *U.S. ex rel. NHCA-TEV, LLC v. Teva Pharm., et al*., No. 17-cv-2040 (E.D. Pa.)
- *U.S. ex rel. SCEF, LLC v. Astra Zeneca PLC, et al.*, No. 17-cv-1328 (W.D. Wash.)
- *U.S. ex rel. Miller, et al. v. AbbVie, Inc*., No. 3:16-cv-2111 (N.D. Tex.)
- *U.S. ex rel. Carle, et al. v. Otsuka Holdings Co., et al*., No. 17-cv-966 (N.D. Ill.)
- *U.S. ex rel. CIMZNHCA v. UCB, Inc., et al.*, No. 3:17-cv-00765 (S.D. Ill.)
- *U.S. ex rel. Health Choice Group, LLC v. Bayer Corp., et al.*, No. 5:17-cv-126 (E.D. Tex.)
- *U.S. ex rel. Health Choice All'nce, LLC v. Eli Lilly & Co., et al.*, No. 5:17-cv-123 (E.D. Tex.)
- *U.S. ex rel. Health Choice Advocates, LLC v. Gilead, et al.*, No. 5:17-cv-121 (E.D. Tex.)[2]

These cases present essentially the same theories of FCA liability – that pharmaceutical companies and commercial outsourcing vendors violated the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), by engaging in so-called "white coat marketing" and by providing free "nurse services" and "reimbursement support services." *See generally* Complaint (Compl.), Dkt. 1, at ¶ 2. More specifically, the complaints allege that the defendants engaged in improper "white coat marketing" by hiring independent contractor nurses to act as undercover sales representatives, who engage in impermissible promotional activity. *See id*. at ¶¶ 70-92. The complaints also allege that the defendants provided illegal remuneration in the form of free nursing services, such as visiting patients at home to provide instruction on how to properly administer their newly-prescribed medications. *See id.* at ¶¶ 93-96. Finally, the complaints

[2] The *Gilead* action was voluntarily dismissed by relators on July 23, 2018. The United States consented to the dismissal "based on its determination that under the circumstances such a dismissal is commensurate with the public interest and that the matter does not warrant the continued expenditure of government resources to pursue or monitor the action[.]"

allege that the pharmaceutical companies violated the AKS by assisting physicians with the completion of insurance documents, such as benefit verifications and prior authorization forms. *See id.* at ¶¶ 97-108.

In preparing its numerous complaints, NHCA Group appears to have utilized the same model or template, repeating certain allegations from one complaint to the next, including seemingly particularized allegations. For example, the relators in this case allege that "for the last half a decade," Amgen sales representatives made a specific "pitch to providers" regarding reimbursement support; notably, the other complaints attribute the exact same message to the other defendants as well:

> **Amgen Compl. ¶ 98:**
> "For the last half a decade, Amgen drug reps' pitch to providers in this regard has essentially been as follows:
>
> > *Dear Doctor: If you prescribe our drug (i.e., "recommend" the patient to use our drug), we will give you the services and resources of a full reimbursement support team to manage the process associated with prescribing the drug. This service will save you the cost and expenses normally associated with managing a patient's prescription and make your practice more profitable."*
>
> **Serono First Amended Compl. ¶ 90:**
> "For the last half a decade, the Drugs Companies' sales representatives' ("Drug Reps.") pitch to providers in this regard has essentially been as follows:
>
> > *Dear Doctor: If you prescribe our drug (i.e., "recommend" the patient to use our drug), we will give you the services and resources of a full reimbursement support team to manage the process associated with prescribing the drug. This service will save you the cost and expenses normally associated with managing a patient's prescription and make your practice more profitable."*
>
> **TEVA First Amended Compl. ¶ 101:**
> "For the last half a decade, TEVA sales representatives' pitch to providers in this regard has essentially been as follows:

> *Dear Doctor: If you prescribe our drug (i.e., "recommend" the patient to use our drug), we will give you the services and resources of a full reimbursement support team to manage the process associated with prescribing the drug. This service will save you the cost and expenses normally associated with managing a patient's prescription and make your practice more profitable."*

UCB Compl. ¶ 73:
"UCB drug representatives' pitch to providers [regarding free reimbursement support] has essentially been as follows:

> *Dear Doctor: If you prescribe our drug (i.e., "recommend" the patient to use our drug), we will give you the services and resources of a full reimbursement support team to manage the process associated with prescribing the drug. This service will save you the cost and expenses normally associated with managing a patient's prescription and make your practice more profitable."*

Similarly, the relators in this case specifically allege that Amgen personnel utilized this reimbursement support "value proposition" messaging to influence prescribing physicians. Yet again this same allegation is repeated nearly verbatim in the other *qui tam* actions:

Amgen Compl. ¶ 99: "This value proposition was a powerful tool in the hands of Amgen's drug reps and used to influence providers to recommend Amgen Covered Drugs."

Serono First Amend Compl. ¶ 91: "This value proposition was a powerful tool in the hands of the Drug Companies' Drug Reps. and used to influence providers to recommend the Drug Companies' drugs."

TEVA First Amended Compl. ¶ 124: "This value proposition was a powerful tool in the hands of TEVA's sales representatives and was used to influence providers to recommend its drug Copaxone over its competitors."

Biogen First Amended Compl. ¶ 203: "This value proposition was a powerful tool in the hands of the Biogen drug representatives, and it was used to induce Prescribers to recommend Avonex, Plegridy and Tysabri."

Eli Lilly Second Amended Compl. ¶ 228: "This value proposition was a powerful tool in the hands of Lilly drug representatives, and used to induce Prescribers to recommend Forteo."

UCB Compl. ¶ 74: "This value proposition was a powerful tool in the hands of UCB's drug representatives and used to influence providers to recommend UCB's Cimzia."

> **Bayer Second Amended Compl. ¶ 215:** "This value proposition was a powerful tool in the hands of the Bayer drug representatives, and it was used to induce Prescribers to recommend Betaseron, Nexavar, and Stivarga."
>
> **Gilead First Amended Compl. ¶ 134:** "This value proposition was a powerful tool in the hands of Gilead's drug reps and Covance's field reps, and was used to induce Prescribers to recommend Gilead drugs."

B. The NHCA Group *Qui Tam* Business Model

Shortly before NHCA Group filed the *qui tam* actions referenced herein, one of its investors, John Mininno, spoke to the media about NHCA Group's business model. *See* J.C. Herz, *Medicare Scammers Steal $60 Billion a Year. This Man is Hunting Them.*, Wired, Mar. 7, 2016, *available at* https://www.wired.com/2016/03/john-mininno-medicare/ (last visited Nov. 30, 2018). Mr. Mininno, described in the article as a "big-data entrepreneur," explained that when the Centers for Medicare and Medicaid Services ("CMS") made vast amounts of Medicare claims data available to the public, he viewed it as "a massive business opportunity," specifically with regard to *qui tam* suits. *Id.* He established NHCA Group with the backing of a "Wall Street angel investor." *Id.*

In order to obtain information for the *qui tam* suits, NHCA Group utilizes a database of resumes, "scraped and extracted from publicly-available sources," which the organization uses to identify "potential informants." *Id.* It then contacts these individuals under the guise of conducting a "qualitative research study" of the pharmaceutical industry, offering to pay each witness for their participation in a standardized interview session. *See* McCabe Decl., ¶ 5 and

Exhibits C-1 – C-3 (exemplar interview transcript excerpts). NHCA Group uses this information obtained under false pretenses to prepare *qui tam* complaints filed by its shell company relators.[3]

On its website, NHCA Group makes no mention of its role behind numerous lawsuits against pharmaceutical companies, instead holding itself out to the public as a "healthcare research company that engages in qualitative research of pharmaceutical and other healthcare-related industries." National Healthcare Analysis Group, http://www.nhcagroup.com (last visited Nov. 30, 2018). And despite lawsuits against pharmaceutical companies being the basis of its profit model, NHCA Group states prominently on its website that it has "no particular bias one way or the other about the industry." *Id.*

The transcripts of NHCA Group witness interviews illustrate NHCA Group's information-gathering model. In them, NHCA Group representatives repeatedly tell witnesses that the organization is conducting a "research study," the aim of which is to analyze the effectiveness of the pharmaceutical industry's "investment" in nurse educators. *See* McCabe Decl., ¶ 5 and Exhibits C-1 – C-3. The interviewers again underscore that "they have no bias one way or the other" regarding the pharmaceutical industry. *Id.* Notably, the witnesses are not told that the interviewer is acting at the direction of attorneys to collect information that will be

[3] All eleven of NHCA Group's *qui tam* actions referenced herein were brought by a corporate relator; however, as is the case here, at least 4 of the cases when originally filed also included an individual co-relator. NHCA Group has also attempted to add individual co-relators to a number of the other cases at the time of subsequent amendments, albeit with limited success. *See, e.g.*, *United States ex rel. Health Choice Group, LLC. v. Bayer Corp., et al.*, No. 5:17-cv-126 (E.D. Tex. July 31, 2018) (dismissing individual co-relator added to amended complaint because her claims "are barred by the False Claims Act's first-to-file rule.").

used in lawsuits involving the witnesses' current or former employers, nor are they told that they will be named as corroborating "witnesses" in those lawsuits.[4]

Utilizing information gleaned from these purported "research studies," NHCA Group advances sweeping allegations of nationwide misconduct by thirty-eight different defendants – allegations that, for Medicare Part D alone, implicate more than 73 million prescriptions written by hundreds of thousands of different physicians for millions of beneficiaries. As a result, the Department of Justice has expended substantial resources investigating these matters.

In this case, after conducting a thorough investigation of relators' allegations and finding them to lack sufficient factual and legal support to justify the immense cost of additional investigation and litigation, the United States notified the Court on June 13, 2018, that it was declining to intervene. *See* Dkt. 9. The United States now respectfully requests that all claims brought on behalf of the United States be dismissed pursuant to 31 U.S.C. § 3730(c)(2)(A), for the reasons discussed below.[5]

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[4] In *United States ex rel. Leysock v. Forest Labs., et al.*, No. 1:12-cv-11354-FDS, 2017 WL 1591833 (D. Mass. April 28, 2017), relator's counsel interviewed witnesses as part of a fictitious "research study" that the court found to be part of "an elaborate scheme of deceptive conduct" designed to obtain specific details to satisfy *qui tam* pleading requirements. *Id*. at *1 The court concluded that such conduct violated several Massachusetts rules of professional conduct and, as a sanction, struck from the complaint all particularized details obtained through the fictitious "research study," and dismissed the complaint. *Id.* at *9-10.

[5] On or about October 3, 2018, counsel for the United States notified relators' counsel of its intention to seek dismissal of this action and the others filed by Venari Partners. Relators' counsel requested an opportunity to discuss the government's concerns, and counsel for the United States thereafter afforded relators' counsel multiple opportunities to meet both in person and telephonically to discuss the government's concerns about the deficiencies in this case and the others. On November 27, 2018, relators in this action requested leave to file an amended complaint. Having had the opportunity to review substantially similar amendments in numerous other cases filed by other Venari Partners, the United States does not believe the newly-added details will change its analysis or request for dismissal.

II. ARGUMENT

A. The FCA Statutory Framework

The FCA enables the United States to recover monies lost due to the submission of false claims. *See* 31 U.S.C. § 3729. Among the unique features of the FCA is that it allows private parties, known as relators, to bring an action on behalf of the United States through the filing of a *qui tam* action. *See id.* at § 3730(b). Although a *qui tam* suit is brought in the name of the United States, a relator has a right to a share of the recovery, plus attorneys' fees and costs. *See id.* at § 3730(b), (d).

Among other things, the FCA directs that the relator must file his or her complaint under seal and serve it, along with a written disclosure of evidence, on the United States. *See id.* at §§ 3730(b)(1) and (2). The United States has 60 days (and any extensions granted by the district court) to investigate the allegations and elect whether or not to intervene in the litigation. *See id.* at §§ 3730(b)(2) and (3). If the United States intervenes in the case, "the action shall be conducted by the Government," and the Government assumes "the primary responsibility for prosecuting the action" and is not bound by an act of the relator. *Id.* at §§ 3730(b)(4)(A) and (c)(1). The relator remains a party to the suit, but the Government may settle the case over his objection, *see id.* at § 3730(c)(2)(B), or may seek to limit his participation in the litigation, *see id.* at § 3730(c)(2)(C).

If the United States declines to intervene in the case, the relator has the right to determine the course of the action. *See id.* at § 3730(c)(3). However, that right is *not* absolute; rather, it is circumscribed by a number of limitations designed to ensure that the United States retains ultimate control over the declined action. For example, the relator cannot dismiss the action without the written consent of the Attorney General. *See id.* at § 3730(b)(1). The court may stay

discovery in the *qui tam* action if it would interfere with the Government's investigation or prosecution of another matter. *See id.* at § 3730(c)(4). Moreover, even when the Attorney General initially declines to intervene in the suit, the district court "may nevertheless permit the Government to intervene at a later date upon a showing of good cause." *Id.* at § 3730(c)(3).

Most importantly for purposes of this motion, the FCA authorizes the Attorney General to dismiss a *qui tam* action over a relator's objection:

> The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

Id. at § 3730(c)(2)(A). The United States is authorized to dismiss even where it has opted not to intervene. *See United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 753 n.10 (9th Cir. 1993), *cert. denied*, 510 U.S. 1140 (1994), *citing Juliano v. Federal Asset Disposition Ass'n*, 736 F. Supp. 348 (D.D.C. 1990), *aff'd*, 959 F.2d 1101 (D.C. Cir. 1992) (table).

B. Standard of Review

The Government possesses broad authority to dismiss a *qui tam* action under § 3730(c)(2)(A), and appellate courts have adopted two independent, highly deferential standards to guide the application of the government's dismissal authority. In *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003), the District of Columbia Circuit interpreted the FCA to grant the Government "an unfettered right to dismiss" a *qui tam* action. The Ninth Circuit requires a "rational relationship" for dismissal but recognizes in assessing that relationship that the United States has broad prosecutorial discretion to dismiss even meritorious *qui tam* cases if the reasons for dismissal are rationally related to a legitimate government interest. *See United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139, 1145 (9th Cir. 1998).

Building on *Sequoia Orange*, the Tenth Circuit has concluded that ". . .[‘] it is enough that there are plausible, or arguable, reasons supporting the agency decision [to move for dismissal].’" *Ridenour v. Kaiser-Hill Co., L.L.C.*, 397 F.3d 925, 937 (10th Cir. 2005) (citing the district court decision in *Sequoia Orange*, 912 F. Supp. 1325, 1341 (E.D. Cal. 1995)). The Third Circuit has yet to adopt a standard for dismissal under section 3730(c)(2)(A). However, in *United States ex rel. Surdovel v. Digirad Imaging Solutions*, No. 07–0458, 2013 WL 6178987, at *2 (E.D. Pa. Nov. 25, 2013), before granting the government's motion to dismiss, the district court observed that both tests are "extremely deferential" to the United States.

As explained below, the more recent *Swift* standard better comports with the FCA's statutory text and framework, as well as the well-established deference due to the Government's exercise of prosecutorial discretion. Under either standard, however, dismissal is warranted in this case.

C. The Court Should Recognize the Government's Unfettered Right to Dismiss a Declined *Qui Tam* Action

Consistent with *Swift*, this Court should find that the United States has an unfettered right to dismiss a *qui tam* suit and defer to the United States' decision to dismiss.

As the *Swift* court explained, the FCA operates against the backdrop of the general principle of separation of powers, in which the Executive Branch exercises control over whether to pursue litigation for the United States. *Swift*, 318 F.3d at 251-52. The court concluded that full deference to the Executive Branch is particularly appropriate, observing that "we cannot see how § 3730(c)(2)(A) gives the judiciary general oversight of the Executive´s judgment in this regard," given that "'[t]he Government'—meaning the Executive Branch, not the Judicial—'may dismiss the action,' which at least suggests the absence of judicial constraint." 318 F.3d at 252. The *Swift* court further held that the

Government's decision not to prosecute a case that is brought in its name is "unreviewable," including decisions to dismiss under § 3730(c)(2)(A). *Id.*

As the D.C. Circuit concluded in *Swift*, imposing judicial review on the Executive's litigation determinations is inconsistent with the general principle of separation of powers: "decisions not to prosecute, which is what the government's judgment in this case amounts to, are unreviewable." *Id.* Thus, the appellate court concluded, under § 3730(c)(2)(A), the Attorney General has an "unfettered right to dismiss an action." *Id.*; *see also id.* at 253 ("The decision whether to bring an action on behalf of the United States is therefore 'a decision generally committed to [the Government's] absolute discretion' for the reasons spelled out in *Heckler v. Chaney*, 470 U.S. at 831").

The *Swift* court also rejected the notion that a relator's right to a hearing, as provided in § 3730(c)(2)(A), was intended to confer authority on the court to review the Government's reasons for dismissal. *Id.* at 253. It explained that nothing in the FCA "purports to deprive the Executive Branch of its historical prerogative to decide which cases should go forward in the name of the United States." *Id.* Instead, the *Swift* court concluded that the function of a hearing, if requested by relator, "is simply to give the relator a formal opportunity to convince the government not to end the case." *Id.*

The *Swift* standard is also more consistent with the plain language of § 3730(c)(2)(A), which differs markedly from the provision in the statute authorizing the Attorney General to settle a *qui tam* case over a relator's objection: "The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, *that the proposed settlement is fair, adequate, and reasonable under all the circumstances*." 31 U.S.C. § 3730(c)(2)(B) (emphasis added). Significantly,

§ 3730(c)(2)(A) imposes no similar limitation on the Attorney General's authority to dismiss a *qui tam* case.

The Attorney General's broad dismissal authority in the statute also sharply contrasts with the ability of a relator to dismiss a *qui tam* case. The FCA specifically states that the relator has no such power unless "the court and the Attorney General give written consent to the dismissal and their reasons for consenting." *Id.* at § 3730(b)(1). Once again, no such restrictions appear in § 3730(c)(2)(A).

It is not surprising that Congress gave unfettered discretion to the Attorney General to determine whether a *qui tam* case should be prosecuted. A *qui tam* relator has been authorized by Congress to sue solely to seek recovery of injuries suffered by the United States, not by the relator. As the Supreme Court made clear in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765 (2000), a relator has Article III standing because she can be regarded as having received a "partial assignment from Congress of the Government's damages." *Id*. at 773, 772-74. Specifically, a relator has standing "to assert the injury in fact suffered by the assignor [United States]." *Id*. Thus, a relator herself has suffered no cognizable injury warranting the continuation of a suit opposed by the United States. *See id*. at 773.

D. Dismissal is Also Warranted Under *Sequoia Orange's* Rational Relationship Test

While the United States submits that *Swift*'s unfettered discretion reflects the appropriate construction of § 3730(c)(2)(A), the court need not resolve that issue, because dismissal is also warranted under the rational relationship test articulated in *Sequoia Orange*. Under this standard, the United States need only (1) identify a "valid government purpose" for dismissing the case, and (2) show a "rational relation between dismissal and accomplishment of the purpose." *Sequoia Orange*, 151 F.3d at 1145 (quotations omitted). If the United States satisfies

this two-step test, "the burden switches to the relator to demonstrate that dismissal is fraudulent, arbitrary and capricious, or illegal." *Id*.

In developing this test, the Ninth Circuit observed that "the decision to dismiss has been likened to a matter within the government's prosecutorial discretion in enforcing federal laws," and the dismissal provision in the FCA should not be construed to grant the judiciary an impermissible power to approve or disapprove the Executive's exercise of prosecutorial discretion. *Id*. at 1143. Consequently, the Ninth Circuit reasoned that when a court considers a motion by the government to dismiss a *qui tam* case, it should "respect[] the Executive Branch's prosecutorial authority by requiring no greater justification of the dismissal motion than is mandated by the Constitution itself." *Id.* at 1146. As a result, even where the *Sequoia* standard is applied, courts are careful not to create barriers to the Government's exercise of its prosecutorial discretion. As this district court has noted, even under the *Sequoia* standard, the government "need only show that its decision to dismiss the case is neither arbitrary nor irrational." *United States ex rel. Surdovel*, 2013 WL 6178987, at *2.

Numerous courts, including the Ninth Circuit in *Sequoia*, have acknowledged that litigation costs represent a valid government interest and the Government may therefore rationally seek dismissal of an action even where the allegations may have merit. *See Sequoia Orange*, 151 F.3d at 1146 (approving of district court's consideration of "the burden imposed on the taxpayers by its litigation" and "internal staff costs" the government would incur with relator's litigation); *Swift*, 318 F.3d at 254 ("[T]he government's goal of minimizing its expenses is still a legitimate objective, and dismissal of the suit furthered that objective."); *United States ex rel. Stovall v. Webster Univ.*, No. 3:15-CV-03530-DCC, 2018 WL 3756888, at *3 (D.S.C., Aug. 8, 2018) (granting the government's motion to dismiss because "dismissal will further its

interest in preserving scarce resources by avoiding the time and expense necessary to monitor this action"); *see also United States ex rel. Levine v. Avnet, Inc.*, No. 2:14-cv-17, 2015 WL 1499519, at *5 (E.D. Ky. Apr. 1, 2015) (same); *United States ex rel. Nicholson v. Spigelman*, No. 10-cv-3361, 2011 WL 2683161, at *2 (N.D. Ill. July 8, 2011) (same).

In this case dismissal is appropriate because it is rationally related to the valid governmental purposes of preserving scarce government resources and protecting important policy prerogatives of the federal government's healthcare programs. As an initial matter, based on its extensive investigation of the various complaints filed by Venari Partners, the government has concluded that the relators' allegations lack sufficient factual and legal support. The government's investigations included, among other things, the collection and review of tens of thousands documents from the defendants and third parties and interviews of numerous witnesses, including prescribing physicians. The government also has had extensive discussions with relators' counsel and has reviewed various information that they have provided. In addition, the government has consulted with subject-matter experts at HHS-OIG about the relators' allegations and the applicability of regulatory safe harbors and government-issued industry guidance.[6]

As a result, the government has concluded that further expenditure of government resources is not justified. Because relators allege nationwide misconduct involving Medicare, Medicaid, and TRICARE beneficiaries over at least a six-year period, the government will incur substantial costs in monitoring the litigation and responding to discovery requests. For Medicare

[6] To date, Department attorneys in the Civil Division's Fraud Section have collectively spent more than 1,500 hours on the eleven NHCA Group matters referenced herein. This figure does *not* include the substantial time spent by numerous Assistant U.S. Attorneys and attorneys from the Department of Health and Human Services Office of Counsel to the Inspector General, nor does it include the time spent by law enforcement agents, investigators, or auditors.

Part D alone in this period, the Amgen drugs at issue were prescribed more than 3.5 million times by more than 126,000 different physicians treating hundreds of thousands of Medicare beneficiaries. The vast scope of the allegations will necessarily yield substantial, additional investigative and litigation burdens for the United States. These burdens include the expense of collecting, reviewing, processing, and producing documents from among multiple federal healthcare programs, as well as voluminous prescription drug event data and patient health information for potentially thousands of beneficiaries, which, due to its sensitive nature, may require additional (and costly) screening and redaction. Moreover, the government will also have to spend considerable time preparing numerous agency witnesses for depositions and filing statements of interest relating to a variety of legal issues, including the potential need to address Relators' interpretation of the AKS, statutory safe harbors, and HHS-OIG Advisory Opinions.[7] The government has rationally concluded based on its extensive investigation of relators' various cases that the relators' sweeping allegations lack adequate support and are unlikely to yield any recovery sufficient to justify the significant costs and burdens that the government will incur if the cases proceed and the resulting diversion of the government's limited resources away from other more meritorious matters.

In addition, the government has concluded that the specific allegations in this case conflict with important policy and enforcement prerogatives of the federal government's healthcare programs. For instance, relators allege that the provision of educational information and instruction to patients constitutes illegal kickbacks to physicians. But given the vast sums the government spends on the medications at issue, federal healthcare programs have a strong

[7] The expansive scope of the allegations in this case will also impose substantial burdens on the Court, the defendants, and potentially thousands of third-party healthcare providers who are not named as defendants but may get dragged into the case by one or both parties.

interest in ensuring that, after a physician has appropriately prescribed a medication, patients have access to basic product support relating to their medication, such as access to a toll-free patient-assistance line or instructions on how to properly inject or store their medication. In another context, HHS-OIG has advised that the provision of educational materials or informational programs to patients, without more, does not constitute "remuneration." *See* 81 Fed. Reg. 88368-01 at 88396 (Dec. 7, 2016). These relators should not be permitted to indiscriminately advance claims on behalf of the government against an entire industry that would undermine common industry practices the federal government has determined are, in this particular case, appropriate and beneficial to federal healthcare programs and their beneficiaries.

III. CONCLUSION

For the reasons set forth above, this Court should dismiss all claims brought on behalf of the United States by SAPF, LLC and Brian Brousseau under the FCA with prejudice as to Relators and without prejudice as to the United States pursuant to 31 U.S.C. § 3730(c)(2)(A).

Respectfully submitted,

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Dated: December 17, 2018

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CERTIFICATE OF SERVICE

I certify that I caused this document filed through the ECF system to be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants.

Dated: December 17, 2018

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